Amendments to the Claims:

Please cancel claims 1 to 28, 30, 34, 36 to 83 and 173 to 196 without prejudice or disclaimer.

Please add new claims 197 to 243 as follows.

This listing of claims will replace all prior versions and listing of claims in the application.

Claims 1 to 196 (cancelled).

197. (new) A method for reducing the level of active biological contaminants or pathogens in a solid tissue, said method comprising:

(i) adding to said tissue at least one stabilizer selected from the group consisting of ascorbic acid, sodium ascorbate, mannitol, trehalose, dimethylsulfoxide (DMSO), butylatedhyroxytoluene (BHT), dimethylthiourea, glutathione, lipoic acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid (Trolox), uric acid, albumin, histidine, N-acetyl cysteine, tryptophan, N-acetyl-tryptophan, methionine, cysteine, and N-tert-butyl-alpha-phenyl nitrone; and

(ii) irradiating said tissue with a suitable dose of gamma radiation effective to reduce the level of active biological contaminants or pathogens in said tissue.

198. (new) The method of Claim 197 wherein the tissue is hard tissue.

199. (new) The method of Claim 198 wherein the hard tissue is selected from the group consisting of bone, demineralized bone matrix, joints, femurs, femoral heads and teeth.

200. (new) The method of Claim 197 wherein the tissue is soft tissue.

201. (new) The method of Claim 200 wherein the soft tissue is selected from the group consisting of bone marrow, ligaments, tendons, nerves, skin grafts, heart valves, cartilage, corneas, arteries and veins.

202. (new) The method of Claim 197 wherein the tissue is a combination of hard and soft tissue.

203. (new) The method of Claim 197, wherein said tissue is at a temperature below its freezing point during irradiation.

204. (new) The method of Claim 197 wherein said tissue is maintained in an inert atmosphere during irradiation.

205. (new) The method of Claim 204 wherein said tissue is maintained under vacuum during irradiation.

206. (new) A method for reducing the level of active biological contaminants or pathogens in a protein sample, said method comprising:

(i) adding to said protein sample at least one stabilizer selected from the group consisting of ascorbic acid, mannitol, trehalose, dimethylsulfoxide (DMSO), butylatedhyroxytoluene (BHT), dimethylthiourea, glutathione, lipoic acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid (Trolox), uric acid, albumin, histidine, N-acetyl cysteine, tryptophan, N-acetyl-tryptophan, methionine and N-tert-butyl-alpha-phenyl nitrone; and

(ii) irradiating said protein sample with a suitable dose of gamma radiation effective to reduce the level of active biological contaminants or pathogens in said protein sample.

207. (new) The method of Claim 206, wherein said protein sample is at a temperature below its freezing point during irradiation.

208. (new) The method of Claim 206 wherein the protein sample is maintained in an inert atmosphere during irradiation.

209. (new) The method of Claim 208 wherein the protein sample is maintained under vacuum during irradiation.

210. (new) The method of Claim 206 wherein the protein sample contains one or more proteins.

211. (new) The method of Claim 206 wherein the protein is an antibody, immunoglobulin, hormone, growth factor, anticoagulant, clotting factor or complement protein.

212. (new) The method of Claim 211 wherein the clotting factor is selected from the group consisting of Thrombin, Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand Factor, Fibrin and Fibrinogen.

213. (new) The method of Claim 211 wherein the immunoglobulins are polyclonal or monoclonal immunoglobulins or mixtures thereof.

214. (new) The method of Claim 213 wherein the immunoglobulins are immunoglobulin G, immunoglobulin M, immunoglobulin A, immunoglobulin E or mixtures thereof.

215. (new) The method of Claim 206 wherein the protein is selected from the group consisting of protein C, protein S, alpha-1 anti-trypsin (alpha-1 protease inhibitor), heparin, insulin, butyl-cholinesterase, warfarin, streptokinase, tissue plasminogen activator (TPA), erythropoietin (EPO), urokinase, neupogen, antithrombin-3, alpha-glucosidase and albumin.

216. (new) The method of Claim 206 wherein the protein is produced by recombinant methods.

217. (new) A method for reducing the level of active biological contaminants or pathogens in plasma or serum, said method comprising:

(i) adding to said plasma or serum at least one stabilizer selected from the group consisting of ascorbic acid, sodium ascorbate, mannitol, trehalose, dimethylsulfoxide (DMSO), butylatedhyroxytoluene (BHT), dimethylthiourea, glutathione, lipoic acid, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid (Trolox), uric acid, albumin, histidine, N-acetyl cysteine, tryptophan, N-acetyl-tryptophan, methionine, cysteine, and N-tert-butyl-alpha-phenyl nitrone; and

(ii) irradiating said plasma or serum with a suitable dose of gamma radiation effective to reduce the level of active biological contaminants or pathogens in said plasma or serum.

218. (new) The method of Claim 217 wherein the serum is fetal bovine serum.

219. (new) The method of Claim 217, wherein said plasma or serum is at a temperature below its freezing point during irradiation.

220. (new) The method of Claim 217 wherein the plasma or serum is maintained in an inert atmosphere during irradiation.

221. (new) The method of Claim 220 wherein the plasma or serum is maintained under vacuum during irradiation.

222. (new) The method according to Claim 197, 206 or 217, wherein said irradiation is applied at a rate of at least about 3.0 kGy/hour to at least about 30.0 kGy/hour.

223. (new) The method of Claim 197, 206 or 217, wherein the total dose of gamma irradiation is at least about 45 kGy.

224. (new) The method of Claim 197, 206 or 217, wherein the concentration of the stabilizer is at least 20 mM.

225. (new) The method of Claim 197, 206 or 217, wherein the concentration of the stabilizer is at least 50 mM.

226. (new) The method of Claim 197, 206 or 217, wherein the concentration of the stabilizer is at least 100 mM.

227. (new) The method of Claim 197, 206 or 217 wherein the one or more stabilizers is DMSO.

228. (new) The method of Claim 197, 206 or 217 wherein the one or more stabilizers is mannitol.

229. (new) The method of Claim 197, 206 or 217 wherein the one or more stabilizers is trehalose.

230. (new) The method of Claim 197, 206 or 217, wherein a combination of two or more stabilizers is added to said tissue, protein sample, plasma or serum.

231. (new) The method of Claim 230, wherein two or more stabilizers are selected from the group consisting of DMSO, mannitol and trehalose.

232. (new) The method of Claim 231, where the two or more stabilizers are DMSO and mannitol.

233. (new) The method of Claim 197, 206 or 217, further comprising contacting the tissue, protein sample, plasma or serum with one or more sensitizers.

234. (new) The method of Claims 197 or 206 wherein the tissue or protein sample contains one or more residual solvents.

235. (new) The method of Claim 234 wherein the residual solvent is water.

236. (new) The method of Claim 234 wherein the residual solvent is an organic solvent.

237. (new) The method of Claim 236 wherein the organic solvent is selected from the group consisting of ethanol, isopropanol and polyethylene glycol.

238. (new) The method of Claim 234 wherein the residual solvent content is reduced by lyophilization.

239. (new) The method of Claim 238 wherein the residual solvent content is less than 8.0 percent.

240. (new) The method of Claim 238 wherein the residual solvent content is less than 6.0 percent.

241. (new) The method of Claim 238 wherein the residual solvent content is less than 1.0 percent.

242. (new) The method of Claim 238 wherein the residual solvent content is less than 0.5 percent.

243. (new) The method of Claim 197, 206 or 217, wherein the tissue, protein sample or plasma or serum is irradiated for a sufficient amount of time to reduce the level of one or more biological contaminants in the tissue, protein sample, plasma or serum.

Summary of the Office Action

1. Claims 183, 185 and 187 were objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

2. Claims 1, 2, 5, 13 to 15, 18, 20 to 22, 25 to 28, 30, 34, 37, 45 to 47, 50, 52 to 54, 57, 60, 68, 70, 73, 75 to 77, 80 to 83, 176 and 179 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Sakai *et al.*

3. Claims 1, 2, 4 to 8, 14, 19, 21, 22, 25 to 28, 30, 34, 36 to 40, 46, 51, 53, 54, 57, 59 to 63, 69, 74, 76, 77, 80 to 83, 177, 180, 188 to 196 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Chanderkar *et al.*

4. Claims 1, 2, 4 to 6, 9, 14, 18, 20 to 23, 25 to 28, 182 and 183 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Baquey *et al.*

5. Claims 1, 2, 5 10, 14, 19, 22 and 25 to 28 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Field *et al.*

6. Claims 3, 58, 173 to 175, 177 and 178 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sakai *et al.* in view of Horowitz *et al.*

7. Claims 4, 6, 11, 12, 16, 17, 36, 38, 43, 44, 48, 49, 59, 66, 67, 71 and 72 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sakai *et al.*

8. Claims 58, 173 and 175 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Chanderkar *et al.* in view of Horowitz *et al.*

9. Claims 3, 30, 34, 36 to 38, 41, 46, 50, 52 to 61, 64, 69, 73, 75 to 83, 173 to 181 and 184 to 187 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Baquey *et al.* in view of Horowitz *et al.*

10. Claim 24 was rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Baquey *et al.*

11. Claims 3, 30, 34, 37, 42, 46, 51, 57, 58, 60, 65, 69, 74, 77, 80 to 83 and 173 to 181 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Field *et al.* in view of Horowitz *et al.*

Remarks

The Advisory Office Action dated June 22, 2004 along with the Office Action dated November 19, 2003 have been carefully reviewed and the foregoing remarks are made in response thereto.

Applicants appreciate the comments of the Examiner relating to her interpretation of the term "tissue" as set forth in the Advisory Office Action. While Applicants respectfully disagree with the comments of the Examiner, Applicants have considered these remarks when drafting claim 197. In view of the above claim amendments and following remarks, Applicants respectfully request reconsideration and reexamination of this application and timely allowance of the pending claims.

By this Amendment, claims 1 to 28, 30, 34, 36 to 83 and 173 to 196 have been cancelled and claims 197 to 243 have been added. Applicants respectfully submit that no new prohibited matter has been introduced by the amendments to the claims. While written description support for the substitute claims can be found throughout the specification and in the original claims, examples of specific support for the additional claims can be found in the original claims and specification as set forth in the table below.

Claim No.	**Support in the Specification and in the Original Claims**
197	page 4, lines 12-19; page 5, lines 26-29;
197 (i)	page 8, line 4 to page 9, line 15
197 (ii)	page 11, lines 15-24; page 13, lines 28-33; Claim 14
198-202	page 5, lines 11-25; Claim 10
203, 207, 219	page 13, lines 11-16; page 15, lines 5-12
204, 205, 208, 209, 220, 221	page 13, lines 22-27
206	page 4, lines 12-19; page 5, lines 6-11
206 (ii)	page 8, line 4 to page 9, line 15
206 (ii)	page 11, lines 15-24; page 13, lines 28-33; Claim 14
210	page 5, lines 6-11; page 6, lines 28-30; page 30, lines 23-24; page 31, lines 16-17
211	page 6, lines 16-23; page 10, line 21 to page 11, line 14
212	page 6, line 28 to page 7, line 14; Claim 8
213	page 11, lines 10-12
214	page 29, lines 23-24; Claim 9
215	page 10, line 30 to page 11, line 14
216	page 10, lines 21-30; Claim 11
217	page 4, lines 12-19; page 6, lines 16-23; page 7, lines 15-20
217 (ii)	page 8, line 4 to page 9, line 15
217 (ii)	page 11, lines 15-24; page 13, lines 28-33; Claim 14
218	page 7, lines 15-20; page 11, lines 9-10
222	page 14, lines 20-24; Claims 19-22
223	page 16, lines 22-24
224-236	page 4, lines 14-17, lines 25-27
227	page 9, line 7

Claim No.	Support in the Specification and in the Original Claims
228	page 8, line 25
229	page 8, line 27
230	page 12, lines 4-6, lines 14-16
231, 232	page 8, lines 25-27; page 9, line 7
233	page 9, line 31 to page 10, line 20
234	page 9, lines 16-30
235	page 9, line 19
236-237	page 9, lines 19-20
238	page 13, lines 17-22
239-242	page 12, line 26 to page 13, line 6
243	page 4, lines 9-11, lines 17-19, lines 27-30; page 11, lines 31-33

Rejection based on 37 C.F.R. 1.75(c)

Claims 183, 185 and 187 were objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the objection.

Rejections based on 35 U.S.C. 102(b)

Claims 1, 2, 5, 13 to 15, 18, 20 to 22, 25 to 28, 30, 34, 37, 45 to 47, 50, 52 to 54, 57, 60, 68, 70, 73, 75 to 77, 80 to 83, 176 and 179 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Sakai *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. With regard to the substitute claims, Applicants submit that the cited reference does not teach all of the limitations of the substitute claims. Specifically, the cited reference does not disclose the use of L-cysteine in solid tissues, serum or plasma as set forth in claims 197 and 217.

Claims 1, 2, 4 to 8, 14, 19, 21, 22, 25 to 28, 30, 34, 36 to 40, 46, 51, 53, 54, 57, 59 to 63, 69, 74, 76, 77, 80 to 83, 177, 180, 188 to 196 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Chanderkar *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. With regard to the substitute claims, Applicants submit that the cited reference does not teach all of the limitations of the substitute claims. Specifically, the cited reference does not disclose the use of the stabilizers set forth in claims 197, 206 and 217.

Claims 1, 2, 4 to 6, 9, 14, 18, 20 to 23, 25 to 28, 182 and 183 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Baquey *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. With regard to the substitute claims, Applicants submit that the cited reference does not teach all of the limitations of the substitute claims. Specifically, the cited reference does not disclose the use of the stabilizers recited in the substitute claims.

Claims 1, 2, 5 10, 14, 19, 22 and 25 to 28 were rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Field *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. With regard to the substitute claims, Applicants submit that the cited reference does not teach all of the limitations of the substitute claims. Specifically, the cited reference does not disclose the use of the stabilizers set forth in the substitute claims.

Rejections based on 35 U.S.C. 103(a)

Claims 3, 58, 173 to 175, 177 and 178 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sakai *et al.* in view of Horowitz *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. Applicants have addressed Sakai *et al.* above but with regard to Horwitz *et al.*, Applicant submit that this reference does not disclose any of the stabilizers in the substitute claims and therefore does not suggest their use.

Claims 4, 6, 11, 12, 16, 17, 36, 38, 43, 44, 48, 49, 59, 66, 67, 71 and 72 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Sakai *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. As indicated above, Applicants submit that the cited references do not disclose nor suggest any of the stabilizers recited in the substitute claims.

Claims 58, 173 and 175 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Chanderkar *et al.* in view of Horowitz *et al.* Applicants have cancelled these claims without prejudice or disclaimer and without acquiescing to the merits of the rejection, therefore the rejection is moot. As indicated above, Applicants submit that the cited references do not disclose nor suggest any of the stabilizers recited in the substitute claims.